

17648 U.S. PTO
102003

Practitioner's Docket No. SP-1159C.2

PATENT

17497 J.S. PTO
10/683197
102003

Preliminary Classification:
Proposed Class:
Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example "Proposed Class 2,- subclass 129." " M.P.E.P. § 601, 7th ed.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s):

WARNING: 37 C.F.R. § 1.41(a)(1) points out:

"(a) A patent is applied for in the name or names of the actual inventor or inventors.
"(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.63, except as provided for in § 1.53(d)(4) and § 1.63(d). If an oath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name or names of the inventor or inventors."

For (title):
Method of Reducing Low Density Lipoprotein Concentration

Express Mailing Under 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
Express Mail Certification is optional.)

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date 10/20/2003, in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231 as "Express Mail Post Office to Addressee" Mailing Label No. EV_042962849 US

Tonya Walker
(type or print name of person mailing paper)

Tonya Walker
Signature of person certifying

Warning: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

Warning: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b). "Since the filing of correspondence under § 1.10 with out the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition. "Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439 at 56,442.

(New Application Transmittal [4-1] - page 1 of 15)

1. Type of Application

This new application is for a(n)

(check one applicable item below)

☒ Original (nonprovisional)

☐ Design

☐ Plant

WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. § 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

WARNING: Do not use this transmittal for the filing of a provisional application.

NOTE: If one of the following 3 items apply, then complete and attach *ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED* and a *NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION*.

☒ Divisional.

☐ Continuation.

☐ Continuation-in-part (C-I-P).

2. Benefit of Prior U.S. Application(s) (35 U.S.C. §§ 119(e), 120, or 121)

NOTE: "A nonprovisional application or international application designating the United States of America may claim an invention disclosed in one or more prior-filed copending nonprovisional applications or international applications designating the United States of America. In order for an application to claim the benefit of a prior-filed copending nonprovisional application or international application designating the United States of America, each prior-filed application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed application must be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in § 1.51(b); or

(iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or

(iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) within the time period set forth in § 1.53(f).

37 C.F.R. § 1.78(a)(1).

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§ 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C. § 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(New Application Transmittal [4-1] --page 2 of 15)

WARNING: 37 C.F.R. § 1.78(a)(2) deals with the time in which the claim for the benefit of an earlier filing date must be made and states:

“(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application. The time periods in this paragraph do not apply if the later-filed application is:

- (A) An application for a design patent;
- (B) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or
- (C) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title.

(iv) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number.”

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

[X]The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

3. Papers Enclosed

- A. Required for filing date under 37 C.F.R. § 1.53(b) (Regular) or 37 C.F.R. § 1.153 (Design) Application

Pages of specification 31

Pages of claims 1

Sheets of drawing 3

WARNING: **DO NOT** submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. § 1.84, see Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: ``Identification of drawings. Identifying indicia, if provided, should include the title of the invention, inventor's name and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin."

(complete the following, if applicable)

☐ The enclosed drawing(s) are photograph(s).

NOTE: 37 C.F.R. 1.84

``(b) Photographs.

``(1) Black and white. Photographs, including photocopies of photographs, are not ordinarily permitted in utility and design patent applications. The Office will accept photographs in utility and design patent applications, however, if photographs are the only practicable medium for illustrating the claimed invention. For example, photographs or photomicrographs of: electrophoresis gels, blots (e.g., immunological, western, Southern, and northern), auto radiographs, cell cultures (stained and unstained), histological tissue cross sections (stained and unstained), animals, plants, in vivo imaging, thin layer chromatography plates, crystalline structures, and, in a design patent application, ornamental effects, are acceptable. If the subject matter of the application admits of illustration by a drawing, the examiner may require a drawing in place of the photograph. The photographs must be of sufficient quality so that all details in the photographs are reproducible in the printed patent.

``(2) Color photographs. Color photographs will be accepted in utility and design patent applications if the conditions for accepting color drawings and black and white photographs have been satisfied. See paragraphs (a)(2) and (b)(1) of this section."

☐ The enclosed drawing(s) are in color. Three (3) sets of color drawings and a **``PETITION TO ACCEPT COLOR DRAWING(S)''** are attached. 37 C.F.R. §§ 1.84(a)(2) and 1.84(b).

NOTE: 37 C.F.R. 1.84(a)

``(2) Color. On rare occasions, color drawings may be necessary as the only practical medium by which to disclose the subject matter sought to be patented in a utility or design patent application or the subject matter of a statutory invention registration. The color drawings must be of sufficient quality such that all details in the drawings are reproducible in black and white in the printed patent. Color drawings are not permitted in international applications (see PCT Rule 11.13), or in an application, or copy thereof, submitted under the Office electronic filing system. The Office will accept color drawings in utility or design patent applications and statutory invention registrations only after granting a petition filed under this paragraph explaining why the color drawings are necessary. Any such petition must include the following:

- (i) The fee set forth in § 1.17(h);
- (ii) Three (3) sets of color drawings;
- (iii) A black and white photocopy that accurately depicts, to the extent possible, the subject matter shown in the color drawing; and
- (iv) An amendment to the specification to insert (unless the specification contains or has been previously amended to contain) the following language as the first paragraph of the brief description of the drawings:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee."

☐ formal

☒ informal

B. Other Papers Enclosed

 1 Pages of declaration and power of attorney

 1 Pages of abstract

 Other

4. Additional papers enclosed

☐ Amendment to claims

☐ Cancel in this applications claims _____ before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

☐ Add the claims shown on the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims.)

☒ Preliminary Amendment

☒ Information Disclosure Statement (37 C.F.R. § 1.98)

NOTE: 37 C.F.R. § 1.97 (b) An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) Before the mailing of a first Office action on the merits; or

WARNING: In order to ensure consideration of information previously submitted but which has not been considered in the parent application, an applicant must resubmit the information, complying with 37 C.F.R. § 1.97 and 37 C.F.R. § 1.98, in the continuing application filed under 37 C.F.R. § 1.53(b). See § 609B(3), M.P.E.P., 7th Edition, Rev. 1.

☒ Form PTO-1449 (PTO/SB/08A and 08B)

☒ Citations

☐ Declaration of Biological Deposit

☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.

☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative

☐ Special Comments

☐ Other

5. Declaration or oath (including power of attorney)

NOTE: A newly executed declaration is not required in a continuation or divisional application provided that the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under § 1.47, then a copy of that declaration must be filed accompanied by a copy of the decision granting § 1.47 status or, if a nonsigning person under § 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. §§ 1.63(d)(1)-(3).

NOTE: A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name including family name and at least one given name, without abbreviation together with any other given name or initial, and the residence, post office address and country or citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 C.F.R. § 1.63(a)(1)-(4) .

NOTE: "The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.62, except as provided for in § 1.53(d)(4) and § 1.63(d). If an oath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name or names of the inventor or inventors." 37 C.F.R. § 1.41(a)(1) .

☒ Enclosed

Executed by

(check all applicable boxes)

☒ inventor(s).

☐ legal representative of inventor(s). 37 C.F.R. §§ 1.42 or 1.43 .

☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

☐ This is the petition required by 37 C.F.R. § 1.47 and the statement required by 37 C.F.R. § 1.47 is also attached. See item 13 below for fee.

☐ Not Enclosed.

NOTE: Where the filing is a completion in the U.S. of an International Application or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing *ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED*.

☒ Application is made by a person authorized under 37 C.F.R. § 1.41(c) on behalf of all the above named inventor(s).

(The declaration or oath, along with the surcharge required by 37 C.F.R. § 1.16(e) can be filed subsequently).

☐ Showing that the filing is authorized.

(not required unless called into question. 37 C.F.R. § 1.41(d))

6. Inventorship Statement

WARNING: If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

☒ The same.

or

☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,

☐ is submitted.

☐ will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of \$130.00 required by 37 C.F.R. § 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 C.F.R. § 1.52(d) .

☒ English

☐ Non-English

☐ The attached translation includes a statement that the translation is accurate. 37 C.F.R. § 1.52(d) .

(New Application Transmittal [4-1]--page 6 of 15)

8. Assignment

☒ An assignment of the invention to The Solae Company, LLC.

☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

☒ will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: A newly executed "CERTIFICATE UNDER 37 C.F.R. § 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.

☐ This is a ☐ continuation ☐ divisional application and the assignment document for the parent application 10 /461,751 was filed on 6/13/03.

9. Certified Copy

Certified copy(ies) of application(s)

| | | |
|------------------|--------|-----|
| Country Filed | Appln. | No. |
| Country Filed | Appln. | No. |
| Country Filed | Appln. | No. |

from which priority is claimed

☐ is (are) attached.

☐ will follow.

NOTE: 37 C.F.R. § 1.55 Claim for foreign priority.

"(a) ***

(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time periods in this paragraph do not apply in an application under 35 U.S.C. 111(a) if the application is:

(A) A design application; or

(B) An application filed before November 29, 2000.

(c) Unless such claim is accepted in accordance with the provisions of this paragraph, any claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) not presented within the time period provided by paragraph (a) of this section is considered to have been waived. If a claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) is presented after the time period provided by paragraph (a) of this section, the claim may be accepted if the claim identifying the prior foreign application by specifying its application number, country (or intellectual property authority), and the day, month, and year of its filing was unintentionally delayed. A petition to accept a delayed claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) must be accompanied by:

New Application Transmittal [4-1] --page 7 of 15)

- (1) The claim under 35 U.S.C. 119(a)-(d) or 365(a) and this section to the prior foreign application, unless previously submitted;
- (2) The surcharge set forth in § 1.17(t); and
- (3) A statement that the entire delay between the date the claim was due under paragraph (a)(1) of this section and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional."

NOTE: 37 C.F.R. § 1.63 Oath or declaration.

“(a) An oath or declaration filed under § 1.51(b)(2) as a part of a nonprovisional application must:

• ***

(c) Unless such information is supplied on an application data sheet in accordance with § 1.76, the oath or declaration must also identify:

- (2) Any foreign application for patent (or inventor's certificate) for which a claim for priority is made pursuant to § 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month, and year of its filing."

The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 C.F.R. § 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. § 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the *ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED*.

10. Fee Calculation (37 C.F.R. § 1.16)

A. ☒ Regular application

| CLAIMS AS FILED | | | |
|---|--------------|------------|---|
| Number filed | Number Extra | Rate | Basic Fee <u>37 C.F.R. § 1.16(a)</u> \$750.00 |
| Total Claims (<u>37 C.F.R. §-1.16(c)</u>) | 3= | × \$ 18.00 | |
| Independent Claims (<u>37 C.F.R. §-1.16(c)</u>) | 1= | × \$ 84.00 | |
| Multiple dependent claim(s), if any (<u>37 C.F.R. § 1.16(d)</u>) | | + \$280.00 | |

☒ Amendment cancelling extra claims is enclosed.

☐ Amendment deleting multiple-dependencies is enclosed.

☐ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. § 1.16(d).

Filing Fee Calculation \$ 750.00

(New Application Transmittal [4-1]--page 8 of 15)

B. [] Design application
(\$330.00--37 C.F.R. § 1.16(f))

Filing Fee Calculation \$ _____

C. [] Plant application
(\$510.00--37 C.F.R. § 1.16(g))

Filing fee calculation \$ _____

11. Assertion of Small Entity Status

[] Applicant hereby asserts status as a small entity under 37 C.F.R. § 1.27

NOTE: 37 C.F.R. § 1.27(c) deals with the assertion of small entity status, whether by a written specific declaration thereof or by payment as a small entity of the basic filing fee or the fee for the entry into the national phase and states:

“(c) Assertion of small entity status. Any party (person, small business concern or nonprofit organization) should make a determination, pursuant to paragraph (f) of this section, of entitlement to be accorded small entity status based on the definitions set forth in paragraph (a) of this section, and must, in order to establish small entity status for the purpose of paying small entity fees, actually make an assertion of entitlement to small entity status, in the manner set forth in paragraphs (c)(1) or (c)(3) of this section, in the application or patent in which such small entity fees are to be paid.

(1) Assertion by writing. Small entity status may be established by a written assertion of entitlement to small entity status. A written assertion must:

(i) Be clearly identifiable;

(ii) Be signed (see paragraph (c)(2) of this section); and

(iii) Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement.

(2) Parties who can sign and file the written assertion. The written assertion can be signed by:

(i) One of the parties identified in § 1.33(b) (e.g., an attorney or agent registered with the Office), § 3.73(b) of this chapter notwithstanding, who can also file the written assertion;

(ii) At least one of the individuals identified as an inventor (even though a § 1.63 executed oath or declaration has not been submitted), notwithstanding § 1.33(b)(4), who can also file the written assertion pursuant to the exception under § 1.33(b) of this part; or

(iii) An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under § 1.33(b) of this part.

(3) Assertion by payment of the small entity basic filing or basic national fee. The payment, by any party, of the exact amount of one of the small entity basic filing fees set forth in §§ 1.16(a), (f), (g), (h), or (k), or one of the small entity basic national fees set forth in §§ 1.492(a)(1), (a)(2), (a)(3), (a)(4), or (a)(5), will be treated as a written assertion of entitlement to small entity status even if the type of basic filing or basic national fee is inadvertently selected in error.

(i) If the Office accords small entity status based on payment of a small entity basic filing or basic national fee under paragraph (c)(3) of this section that is not applicable to that application, any balance of the small entity fee that is applicable to that application will be due along with the appropriate surcharge set forth in § 1.16(e), or § 1.16(l).

(ii) The payment of any small entity fee other than those set forth in paragraph (c)(3) of this section (whether in the exact fee amount or not) will not be treated as a written assertion of entitlement to small entity status and will not be sufficient to establish small entity status in an application or a patent.”

WARNING: 37 C.F.R. § 1.27(c)(4): "Assertion required in related, continuing, and reissue applications. Status as a small entity must be specifically established by an assertion in each related, continuing and reissue application in which status is appropriate and desired. Status as a small entity in one application or patent does not affect the status of any other application or patent, regardless of the relationship of the applications or patents. The refiling of an application under § 1.53 as a continuation, divisional, or continuation-in-part application (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application, requires a new assertion as to continued entitlement to small entity status for the continuing or reissue application."

WARNING: "Small entity status must not be established when the person or persons signing the ... statement can **unequivocally** make the required self-certification." M.P.E.P., § 509.03 (emphasis added).

(complete the following, if applicable)

☐ Status as a small entity was asserted in the prior application _____ / _____, filed on _____, from which benefit is being claimed for this application under:

35 U.S.C.- § ☐ 119(e)
☐ 120
☐ 121
☐ 365(c)

and which status as a small entity is still proper and asserted for this application.

☐ A copy of the written assertion of small entity filed in the prior application is included.

NOTE: A refund based on establishment of small entity status, of a portion of fees timely paid in full prior to establishing status as a small entity may only be obtained if an assertion under § 1.27(c) and a request for a refund of the excess amount are filed within three months of the date of the timely payment of the full fee. The three-month time period is not extendable under § 1.136. 37 C.F.R. § 1.28(a).

Filing Fee Calculation (50% of **A**, **B** or **C** above)

\$ _____

12. Request for International-Type Search (37 C.F.R. § 1.104(d))

(complete, if applicable)

☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

☐ Not Enclosed

☐ No filing fee is to be paid at this time.

(This and the surcharge required by 37 C.F.R. § 1.16(e) can be paid subsequently.)

☒ Enclosed

☒ Filing fee \$ 750.00

☐ Recording assignment

(\$40.00; 37 C.F.R. § 1.21(h))

(See attached "COVER SHEET FOR ASSIGNMENT-
ACCOMPANYING NEW APPLICATION".)

\$ _____

☐ Petition fee for filing by other than all the inventors or person on behalf of
the inventor where inventor refused to sign or cannot be reached

(\$130.00; 37 C.F.R. §§ 1.47 and 1.17(i))

\$ _____

☐ For processing an application with a specification in
a non-English language

(\$130.00; 37 C.F.R. §§ 1.52(d) and 1.17(k))

\$ _____

☐ Processing and retention fee

(\$130.00; 37 C.F.R. §§ 1.53(d) and 1.21(l))

\$ _____

☐ Fee for international-type search report

(\$40.00; 37 C.F.R. § 1.21(e))

\$ _____

NOTE: 37 C.F.R. § 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 C.F.R. § 1.53(f) and this, as well as the changes to 37 C.F.R. §§ 1.53 and 1.78(a)(1) , indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of § 1.21(l) must be paid, within 1 year from notification under § 53(f).

Total fees enclosed \$ 750.00

14. Method of Payment of Fees

☐ Attached is a ☐ check ☐ money order in the amount of \$ _____

☒ Authorization is hereby made to charge the amount of \$ 750.00

☒ to Deposit Account No. 50-0421

☐ to Credit card as shown on the attached credit card information authorization form
PTO-2038.

WARNING: Credit card information should not be included on this form as it may become public.

☒ Charge any additional fees required by this paper or credit any overpayment in the manner
authorized above.

A duplicate of this paper is attached.

(New Application Transmittal **[4-1]** --page 11 of 15)

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

WARNING: Even though small entity status is accorded where the wrong type of small entity basic filing fee or basic national fee is selected but the exact amount of the fee is paid, applicant still needs to pay the correct small entity amount for the basic filing or basic national fee where selection of the wrong type of fee results in a deficiency. While an accompanying general authorization to charge any additional fees suffices to pay the balance due of the proper small entity basic filing or basic national fee, specific authorizations to charge fees under § 1.17 or extension of time fees do not suffice to pay any balance due of the proper small entity basic filing or basic national fee because they do not actually authorize payment of small entity amounts. Changes To Implement the Patent Business Goals; Final Rule [Fed. Reg.: September 8, 2000, pages 54603-54683, at 54611; OG: October 3, 2000, pages 14-39].

☒ The Office is hereby authorized to charge, in the manner shown above, the following additional fees that may be required by this paper and during the entire pendency of this application.

☒ 37 C.F.R. § 1.16(a), (f) or (g) (filing fees)

☐ 37 C.F.R. § 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☐ 37 C.F.R. § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☐ 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a)).

☐ 37 C.F.R. § 1.17 (application processing fees)

NOTE: "...A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application only after the mailing of the notice of allowance. Accordingly, general authorizations to pay fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL-85B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1.311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant and submitted, § 1.311(b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b). Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

NOTE: 37 C.F.R. § 1.28(b) requires ``Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application ... prior to paying, or at the time of paying, ... the issue fee... " From the wording of 37 C.F.R. § 1.28(b), (a) notification of change of status must be made even if the fee is paid as ``other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

NOTE: ``... Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

☒ Credit Account No. 50-0421

☐ Refund

Reg. No. ~~37,278~~ **37, 248**

Tel. No. (314) 982-3004

Customer No.



SIGNATURE OF PRACTITIONER

Richard B. Taylor
(type or print name of attorney)

P. O Box 88940
P.O. Address

St. Louis, MO 63188

☒ Incorporation by reference of added pages

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the *ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED*)

☒ Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added 3

☐ Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added 12

☐ Plus added pages deleting names of inventor(s) named in prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.

Number of pages added _____

☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added _____

☐ Statement Where No Further Pages Added

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

☐ This transmittal ends with this page.



Attorney's Docket No. SP-1159C.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Waggles, et al.
Prior Serial No. : 09/298,528
Prior Filing Date : 4/23/99
Art Unit : 1651
For : Method of Reducing Low Density
Lipoprotein Cholesterol Concentration

Commissioner for Patents
Alexandria, VA 22313-1450

EV042962849US

EXPRESS MAIL CERTIFICATE

"Express Mail" Label Number: EV 042962849 US

Date of Deposit: 10/20/03

I hereby certify that the attached: **Utility Patent Application Transmittal(PTO/SB/05), Fee Transmittal for FY 2003 (PTOSB/17), Combined Declaration and Power of Attorney in Prior Application, Divisional Application Filed Under 37 CFR 1.53 and Preliminary Amendment Application Data Sheet 37 C.F.R. § 1.76, Notification of Filing of Continuing, Divisional, or Continued Prosecution Application, New Application Transmittal and Return Receipt Postcard,** is/are being deposited with the United States Postal Service as "Express Mail" in an envelope addressed to:

**Mail Stop PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

Dated: 10/20/03


Tonya Walker



It is requested that the information disclosed herein be made of record in this application.

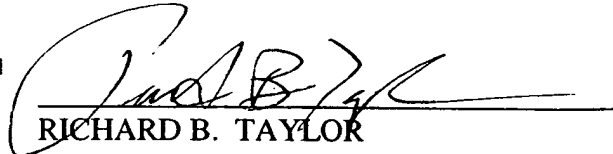
Respectfully submitted,

I hereby certify that this correspondence is being deposited
with the United States Postal Service in an envelope addressed
to: Commissioner for Patents, Washington, D.C. 20231, as
"Express Mail Post Office to Addressee".
Mailing Label No. EV042962680US

Date of Deposit: 10/20/03

Typed Name: ~~Melanie B. Scheidt~~

Signature: Tonya Walker


RICHARD B. TAYLOR
Attorney/Agent for Applicant(s)
Reg. No. 37248

Date: 10/20/03

Telephone No.: 314-982-3004



Practitioner's Docket No. SP-1159C.2

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Waggle et al.

1651

Application No.: 10 / 461,751

Group No.:

Examiner: Ware, D.

Filed: 6/13/03

For: Method of Reducing Low Density Lipoprotein Cholesterol Concentrating

Assistant Commissioner for Patents

XXXXXXXXXXXXXXXXXXXX
Washington, D.C. 20231

Alexandria, VA 22313-1450

**NOTIFICATION OF FILING OF CONTINUING,
DIVISIONAL OR CONTINUED PROSECUTION APPLICATION**

Notification is hereby being made of the filing of a:

- ☐ continuation
- ☐ continuation-in-part
- ☒ divisional
- ☐ continued prosecution

application for this case

☐ concurrently herewith.

☒ on October 20, 2003

Date

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10
(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. § 1.8(a)

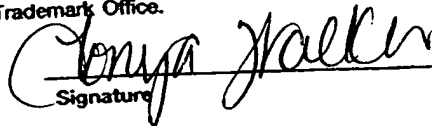
☐ with sufficient postage as first class mail.

37 C.F.R. § 1.10*

☒ as "Express Mail Post Office to Addressee"
Mailing Label No. _____ (mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.


Signature

Date: _____

Tonya Walker

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by Express Mail must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.
(Notification of Filing of Continuing, Divisional or Continued Prosecution Application [4-9] (page 1 of 2))

Practitioner's Docket No. SP-1159C.2

PATENT

**ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF
PRIOR U.S. APPLICATION(S) CLAIMED**

NOTE: See 37 C.F.R. § 1.78.

17. Relate Back

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. § 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. § 120, 121 or 365(c). (35 U.S.C. § 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. § 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(complete the following, if applicable)

☐ Amend the specification by inserting, before the first line, the following sentence:

A. 35 U.S.C. § 119(e)

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)." 37 C.F.R. § 1.78(a)(5).

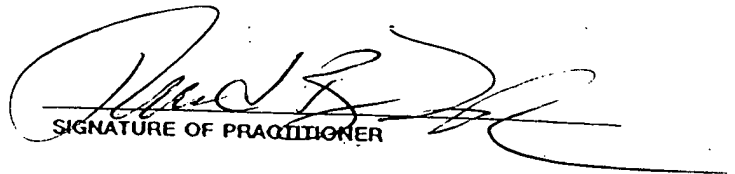
☐ "This application claims the benefit of U.S. Provisional Application(s) No(s):

| APPLICATION NO(S): | FILING DATE |
|--------------------|-------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

Reg. No. 37248

Tel. No.: (314) 982-3004

Customer No.:



SIGNATURE OF PRACTITIONER

Richard B. Taylor

(type or print name of practitioner)

P. O. Box 88940

P.O. Address

St. Louis, MO 63188

B. 35 U.S.C. Sections 120, 121 and 365(c)

WARNING: 37 C.F.R. § 1.78 Claiming benefit of earlier filing date and cross-references to other application.

“(a) . . .

(2) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. This reference must be submitted during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. This time period is not extendable. Unless the reference required by this paragraph is included in an application data sheet (§ 1.76), the specification must contain or be amended to contain such reference in the first sentence following the title. If the application claims the benefit of an international application, the first sentence of the specification must include an indication of whether the international application was published under PCT Article 21(2) in English (regardless of whether benefit for such application is claimed in the application data sheet). The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior application. The identification of an application by application number under this section is the specific reference required by 35 U.S.C. 120 to every application assigned that application number. Cross references to other related applications may be made when appropriate (see § 1.14). Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and this paragraph is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior application. The time period set forth in this paragraph does not apply to an application for a design patent.” (Emphasis added).

- ☒ “This application is a
- ☐ continuation
 - ☐ continuation-in-part
 - ☒ divisional

of copending application(s)

- ☒ application number 0 / 10/461,751 filed on 6/13/03”
- ☐ International Application _____ filed on _____ and which designated the U.S.”
- ☐ The international application was published under PCT Article 21(2) in English (37 C.F.R. § 1.78(a)(2))

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

NOTE: The deadline for entering the national phase in the U.S. for an international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

“The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (f) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application.”

(Added Pages for Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed [4-1.4])

—page 2 of 7)